

CLAIMS

We Claim:

1. An oral pharmaceutical dosage form comprising, in combination, a core, and a coating surrounding the core comprising a resinate of an opiate,
whereby the pharmaceutical oral dosage form is not subject to abuse.
2. The oral pharmaceutical dosage form of claim 1 in which coating is an extended drug release coating.
3. An oral pharmaceutical dosage form of claim 1 in which the coating on the core further comprises the following components:
 - (a) from 1 to 85% by weight of a matrix polymer which is insoluble at a pH of from 1 to 7.5 and contributes to the control of the rate of release of the active ingredient in the stomach and intestines;
 - (b) from 1 to 30% of an enteric polymer which is substantially insoluble at a pH of from 1 to 4, sufficient to delay the release of the active ingredient in the stomach, but which is soluble at a pH of from 6 to 7.5 so as not to substantially delay release in the intestines;
 - (c) from 1 to 60% of a compound soluble at a pH of from 1 to 4, sufficient to enable initiation of release of the active ingredient in the stomach; the percentages being by weight based on the total weight of components (a), (b), and (c); the ratio of the components (a), (b), and (c) in the coating being such that a dose of the pellet composition delivers to the patient a

therapeutically effective amount of the active ingredient over the course of the predetermined interval, so as to maintain an active ingredient blood level at steady state of at least 75% of maximum blood level for more than approximately 4 hours and so that the time at which the active ingredient reaches its maximum concentration is between about 4 and about 30 hours.

4. The oral pharmaceutical dosage form of claim 1 in which the opiate is selected from the group consisting of codeine, dextromoramide, hydrocodone, hydromorphone, pethidine, methadone, morphine, oxycodone, difydrocodeine, fentanyl, and propoxyphene.
5. The oral pharmaceutical dosage form of claim 1 wherein the coating further comprises: as component (a), ethyl cellulose, a quaternary ammonium acrylic or methacrylic polymer, an acrylic or a methacrylic ester copolymer or a mixture thereof; as component (b), cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid:acrylic acid ester copolymer, hydroxypropyl methylcellulose acetate succinate, shellac, cellulose acetate trimellitate and mixtures thereof; and as component (c), polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol having a molecular weight of from 1700 to 20,000, polyvinyl alcohol and monomers therefor and mixtures thereof.

6. The oral pharmaceutical dosage form of claim 6 wherein the coating comprises: 35 to 75% by weight of component (a); 2-20% by weight of component (b); and 15-40% by weight of component (c).
7. The oral pharmaceutical dosage form of claim 7 wherein the coating comprises up to 50% of plasticizer selected from diethyl phthalate, triethyl citrate, triethyl acetyl citrate, triethyl acetin, tributyl citrate, polyethylene glycol having a molecular weight of from 200 to less than 1700 or glycerol and up to 75% of a filler selected from silicon dioxide, titanium dioxide, talc, alumina, starch, kaolin, polacrilin potassium, powdered cellulose and microcrystalline cellulose and mixtures thereof, the percentages being based on the total weight of the coating.
8. The oral pharmaceutical dosage form of claim 7 wherein the coating contains: component (a) 35 to 70%; component (b) 4 to 20%; component (c) 15 to 35%; and, plasticizer 4 to 30%.

9. The oral pharmaceutical dosage form of claim 8 wherein the coating comprises: as component (a), ethyl cellulose, a quaternary ammonium acrylic or methacrylic polymer, an acrylic or a methacrylic ester copolymer or a mixture thereof; as component (b), cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid ester copolymer, hydroxypropyl methylcellulose acetate succinate, shellac, cellulose acetate trimellitate and mixtures thereof; and as component (c), polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol having a molecular weight of from 1700 to 20,000, polyvinyl alcohol and monomers therefore and mixtures thereof.
10. The oral pharmaceutical dosage form of claim 1 in which the oral pharmaceutical dosage form comprises an aversive agent.